DEC 19 2006

Shanghai Ruike Sports Goods CO., LTD.

No. 689, Xinhu Road, Shanghai, China TEL: +86-21-66350714 FAX: +86-21-66351873

510(k) Summary

Device

Trade name: **Ruike 3431 scooter**

Common name: **Electrical scooter**

Classification name: **Motorized three-wheeled vehicle**

Medical specialty (Panel): **Physical Medicine Device**

Regulation number: **890.3800**

Product Code: **89INI**

Classification: **Class II**

Predicate devices

Bewell SC 20 (K043326)/Cycling and Health Tech Industry R&D Center/CHC

Intend use of device

Ruike 3431 scooter is intended for an indoor/outdoor scooter that provides transportation for disabled or elderly persons limited to a seated position.

Device description:

The **Ruike 3431** scooter is an indoor/outdoor transportation vehicles which is battery operated. The movement of the scooter is controlled by a tiller handle and a **thumb operated potentiometer throttle control lever** to engage and disengage the scooter motion in both the forward and reverse directions.

Substantial equivalence:

The **Ruike 3431 scooter** is substantially equivalent to the **Bewell SC 20 (K043326)** manufactured by **Cycling and Health Tech Industry R&D Center/CHC.**

There are minor differences in performance specifications of the scooters, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, **Shanghai Ruike Sports Goods CO., LTD.** believes that the **Ruike 3431** scooter is substantially equivalent to legally marketed devices currently in commercial distribution.

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The substantial equivalence comparison of the Ruike 3431 and Bewell SC 20

	Bewell SC 20(K043326)	Ruike 3431
Intended use	Both scooters are motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.	
Maximum loading	130 kg (286 lbs)	120 kg (265 lbs)
Overall height	1120 mm (44")	825 mm (32.5")
Overall length	1300 mm (51.2")	1030 mm (40.6")
Overall width	610 mm (24")	510mm (20")
Seat overall height	370 mm (14.5")	430 mm (16.9")
Seat overall width	450mm (17.7")	500 mm (19.7")
Seat overall depth	450mm (17.7")	400 mm (15.7")
Seat overall weight	7.5 kg (16.5 lbs)	10 kg (22 lbs)
Motor output	DC24V, 700W, 5000 RPM, 1Pc	180 W x DC 24V, 1Pc
Controller	Dynamic DS72K01	PG S-Drive 45A
Differential mechanism	Differential rate: 20 : 1	Differential rate: 17 : 1
Rear wheel drive	Sealed transaxle direct drive	

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(Continuous) The substantial equivalence comparison of the Ruike 3431 and Bewell SC 20

	Bewell SC 20(K043326)	Ruike 3431
Operation mode	Thumb operated potentiometer throttle control lever	
Battery	Lead-Acid 12V × 36AH × 2PCs	Lead-Acid 12V×24AH×2PCs
Battery level indicator	Yes	Yes
Charger	HP 24V 5AMP (Automatic Type) off-board	2 A (Automatic Type) off-board
Front wheel	12" × 4" Pneumatic tire × 2 PCs Rim: aluminum alloy	192 x 80 mm(7.6"× 3.15") Solid tire x 2 Pcs
Rear wheel	12" × 4" Pneumatic tire × 2 PCs Rim: aluminum alloy	192 x 80 mm(7.6"× 3.15") Solid tire x 2 Pcs
Bumpers	Front: Yes, it's constructed by steel tube Rear : No	Front/Rear: Yes, it's constructed by steel tube
Armrest	Yes, Foldable	
Tiller foldable	Yes	
Backrest recline	Yes	
Recline angle indicator	No	
Headrest	Yes	No
Height adjustable	Yes	No

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(Continuous) The substantial equivalence comparison of the Ruike 3431 and Bewell SC 20

	Bewell SC 20(K043326)	Ruike 3431
Break system	Intelligent regenerative electromagnetic brake	
Braking distance	Forward: 2.58 m(101.6") at max speed	1.05 m(41.3") at max speed
Net weight with battery	97 kg (213 lbs)	51 kg (112 lbs)
Slope grade ability	12 degree	12 degree
Per-charge distance	Up to 35.2 km (22 miles)	14.5 km (9 miles)
Maximum speed	Up to 9 km/hr (5.6 mph), variable	6 km/hr (3.7 mph) , variable
Speed mode	Single mode, Variable	Single mode, Variable
Turning radius	1500 mm (59")	1000 mm (39.4")
Maximum curb height	127 mm (5.0")	45 mm (1.8")
Suspension	Front: Yes, Rear: No	Front: Yes(Optional), Rear: No
Tail lights Signal light	Tail lights and signal lights of the SC 20 and Ruike 3431 scooters have the same functions, but only the styles are different.	
Warning light	Yes	
Horn	Yes	
Anti-tip wheels	Yes	
Disassemble	No	Yes

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shanghai Ruike Sports Goods Co., Ltd.
% Ms. Junnata Chang
14F-2, No. 1, Lane 25
Banqiao, Taipei County,
China (Taiwan) 220

DEC 19 2006

Re: K062645
Trade/Device Name: Ruike 3431
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three wheeled vehicle
Regulatory Class: Class II
Product Code: INI
Dated: December 12, 2006
Received: December 12, 2006

Dear Ms. Junnata Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Device descriptive information

3.1 Statement of indication for use

Statement of Indications for Use

510(k) Number (if known): K062645

Device Name: **Ruike 3431**

Indications for Use:

The **Ruike 3431** scooter is motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.

Prescription Use _____ Over-The-Counter Use __X__

(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

510(k) Number K062645

(Posted November 13, 2003)